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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,050	08/23/2001	Yoav Blatt	BLATT-2	7772

7590 09/16/2003

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EXAMINER
PRATT, HELEN F

ART UNIT	PAPER NUMBER
1761	

DATE MAILED: 09/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/935,050	BLATT ET AL.	
	Examiner	Art Unit	
	Helen F. Pratt	1761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

P riod for R ply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

INFORMATION DISCLOSURE FORM

It is noted that no reference to Goosen et al. as on applicant's IDS has been submitted.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lim et al. (4,389,419) in view of Francois et al. (6,555,544) and Kantor et al. (4,895,725) and Patel et al. (6,569,463).

Lim et al. disclose a process of encapsulating oils and oil soluble substances in microcapsules by forming an emulsion of alkali metal alginate and a filler such as a polysaccharide and an oleophilic substance such as a vitamin, then treating with a solution containing calcium to form beadlets which are washed and dried (abstract and col. 1, lines 34-64). Claim 1 differs from the reference in the steps of reducing the particle size of the lipophilic compound in the presence of a surfactant and in rinsing the beadlet in an acidic solution and in coating the beadlet. Francois et al. disclose a method of making a pharmaceutical composition, combining a surfactant with an active agent and then grinding to submicron sizes (col. 8, lines 45-55). The function of reducing the particle size is that it makes the drugs last longer in humans (col. 3, lines

45-55). The size-reduced particles are suspended in an alginate composition (col. 6, lines 62-70). Rinsing the beadlets in an acid solution and drying is disclosed by Kantor et al. who atomizes an emulsion into an acidic solution. Nothing new is seen in drying the microcapsules, which is routinely done. Patel et al. disclose that it is known to coat a beadlet (col. 41, lines 55-65 and col. 42, lines 14-36 and col. 52, lines 44-55 and col. 60 lines 30-33, lines 44-49). Therefore, it would have been obvious to reduce the size of a lipophilic compound in the presence of a surfactant when combining it with an alginate material because the primary reference is also combining lipophilic compounds with alginate and to rinse the beadlet with an acid and to further coat the beadlet as shown by the combined references.

Claims 2 and 3 require that the particle size of the lipophilic compounds (LC) is not greater than 10 and 20 microns and claim 8 that the size is from 100 to 425. Francois et al. disclose that the LC size is less than 2,000 nm. (col. 6, lines 1-9). Even though this size is not near 10 or 20 microns, it would have been within the skill of the ordinary worker to reduce or enlarge the particle size to whatever size was required depending on the end use, particularly as applicants are claiming small to large sizes. Nothing is seen that this size would have affected any functional characteristics of the lipophilic compound. In fact the reference discloses a type of palmitate, a fat, which is reduced in size (col. 5, lines 10-15). Therefore, it would have been obvious to reduce the LC to less than 10 or 20 microns as shown by the reference.

Claim 4 further requires the use of a particular alginate. However, these types are well known and the reference discloses “alginates” which is the salt form (col. 6,

line 65). Therefore, it would have been obvious to use known forms of alginates in the claimed process.

Claim 5 further requires that a filler be added to stage 1 and claim 7 that it is added at stage ii. Lim et al. disclose that a polysaccharide such as dextrin can be added with the alginate or carboxymethyl cellulose, starches which would have been at stage 2. (col. 2, lines 30-49). Nothing new is seen in adding yet another ingredient to be ground as in stage 1 to achieve the same particle size. Therefore, it would have been obvious to add a filler at stage 1 or 2.

Claim 6 requires particular lipophilic compounds such as fat-soluble vitamins and oils. The reference to Francois et al. disclose a type of palmitate, which is a fat (col. 5, lines 12-13). Therefore, it would have been obvious to use other fat types in the process of the combined references.

Claim 9 further requires particular acids for the aqueous solution. Kantor et al. disclose acids such as ascorbic and lactic as claimed (col. 6, lines 39-44). Therefore, it would have been obvious to use the acids as disclosed by Kantor et al. in the process of the combined references.

Claim 10 requires particular coating materials and claim 11 hydroxypropylene (hpc). Patel et al. disclose the use of fat and cellulose derivatives such as hydroyxypropyl methylcellulose. No difference is seen in this derivative and that of claim 11 at this time (col. 46, lines 5-14, and lines 35-45). Therefore, it would have been obvious to coat with known fats and celluloses.

Water can be in the composition as in claim 12 for size reduction as in step I as disclosed in the reference to Francois et al. (col. 8, lines 44-50). Therefore, it would have been obvious to use water in the size reduction step.

The limitations of claim 13 –16, 18, 20, 21 have been discussed above and are obvious for those reasons.

Claim 19 further requires particular amounts of lipophilic compound in the mixture. Lim et al. disclose the use of from 1-10% vitamin or oil (col. 2, lines 58-63) and Francois et al. disclose the use of a palmitate anti-psychotic agent which is about 3% fat (col. 8, lines 60-70). Therefore, it would have been obvious to a lipophilic compound in the claimed amounts.

Claim 22 requires that the composition is tablet grade. However, it would have been obvious to use ingredients to meet particular specifications.

Claim 23 is to using the lipophilic compounds in food stuff. Lim et al. disclose that their encapsulated vitamins can be used in a foodstuff. Therefore, it would have been obvious to add the composition of the combined references to a foodstuff for the known function of adding at least fat to the foodstuff.

Claim 24 further requires masking the flavor or smell of the fat compound by encapsulating as claimed. However, as the claimed composition has been shown as above, it is obvious that the flavor would have been inherently masked.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen F. Pratt whose telephone number is 703-308-1978. The examiner can normally be reached on Monday to Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Milton Cano, can be reached on (703) 308-3959. The fax phone number for the organization where this application or proceeding is assigned is 703-305-7718.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0651.

Hp 9-10-03

H. Pratt

HELEN PRATT
PRIMARY EXAMINER